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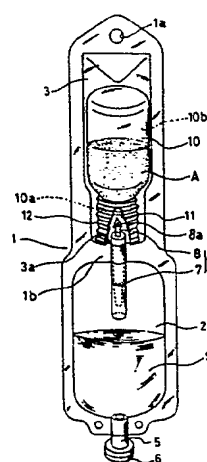
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D-8000 München 80(DE)(54) **SEPARATE STORAGE CONTAINER.**

(57) A communication section (9) has a piercing needle (8) capable of piercing through a piercing section (11) of a solute container (10) storing therein a solute such as a drug, and a closing section (7) which is separable inside a storage chamber (2) storing therein a solvent. The communication section (9) is disposed between the solute container and the storage chamber, and a bellows-like guide cover (12) covers the piercing needle. Accordingly, the piercing needle is positively kept separated from the piercing section when not in use and the guide cover undergoes plastic deformation under an external force exceeding a predetermined value when in use, thereby permitting the piercing operation to be initiated and then maintained. Due to the subsequent separation of the closing section, the solute and the solvent are mixed through the communication sec-

tion and sterile dissolution can be ensured.

FIG. 2



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DESCRIPTION

SEPARATE STORAGE CONTAINER

Technical Field

The present invention relates to a container for separately containing two or more substances, and more particularly, to a separate storage container in which a solvent, such as a solution, in a storage chamber is fed into a solute containing member which contains a solute, such as a powdered or liquid medicine, so that the solute, such as the powdered or liquid medicine, can be mixed and sterilely dissolved.

Background Art

Many of medicines as solutes are dissolved in a solution for use as a solvent immediately before they are administered to a patient by an intravenous injection. There are various reasons for this. A typical reason is that the medicines can maintain their effect only for a short period of time after they are dissolved in the solution. When administering a powdered medicine, such as an antibiotic, contained in a solute vessel for use as a solute containing member, therefore, the following methods have

conventionally been used in general.

In a first example, a suitable amount of a solution, such as a physiological saline solution or 5 % grape sugar injection solution, is sucked in by means of an injector, and the needle of the injector is stuck into a solute vessel containing a powdered medicine, thereby injecting the solution. After the powdered medicine is dissolved, the solution is sucked in again to give a patient an injection.

According to a second example, as is disclosed in Japanese Patent Disclosure No. 59-500600, for example, a solute vessel containing a powdered medicine and a bag stuffed with a solution are sterilely connected by means of an adapter which constitutes communication means holding a piercing needle and a frangible portion, the solution is injected into the solute vessel which contains the powdered medicine, thereby dissolving the powdered medicine, and the resulting solution is returned to the bag to subject a patient to an intravenous drip.

In this case, moreover, a sleeve is given which is disposed so as to surround the piercing needle and is formed of a flexible material which expands and contracts as the needle moves.

According to a third example, as is disclosed in U.S. Pat. No. 4,484, 920, moreover, a solute vessel

containing a powdered medicine, a bag stuffed with a solution, and an empty bag are sterilely connected to one another by means of an adapter which includes a needle and a frangible portion. The solution is put into the solute vessel to dissolve the powdered medicine, whereupon an antibiotic or the like is fully dissolved by using the empty bag as an air vent. The resulting solution is returned to the bag to subject a patient to an intravenous drip.

Also in this case, as in the case of the second example, a flexible, elastic sleeve or boot surrounding the piercing needle is given.

However, the aforementioned prior art examples have various problems to be solved. In the case of the first example, vessels must be provided separately for the solution, injector, and powdered medicine, and must be operated in equipment for sterile work, such as a clean bench, so that the operation is troublesome, and there is a possibility of external bacterial contamination. In the case of the second example, there is no need of the sterile equipment, such as a clean bench, however, since no means is provided for positively keeping the prick portion of the solute vessel containing the powdered medicine separated from the piercing needle on the adapter when not in use in a normal state, so the solute vessel

and the adapter may possibly be connected by mistake. When in use, moreover, the connecting operation is troublesome for an operator, and the construction of the adapter is complicated.

In the case of the third example, moreover, no means is provided for positively keeping the piercing section of the solute vessel separated from the piercing needle on the adapter when not in use, just as in the case of the second example, so that the piercing section may possibly be unexpectedly pierced by mistake, thereby allowing the solute vessel and the adapter to be connected. In the case of this example, furthermore, the solution of the powdered medicine may enter the empty bag during use, and it is not easy to return the resulting solution to the bag containing the solution.

Accordingly, the object of the present invention is to provide a medicine storage container which eliminates the various problems of the prior art separate storage containers described above, and which, despite its simple construction, can positively keep a piercing section of one containing member containing one substance separated from a piercing element capable of piercing the piercing section as required, when not in use in a normal state, and can enable an operator to perform the piercing operation

easily and securely, when in use, so that a chamber for the one containing member and a chamber for the other containing member containing the other substance are sterilely connected to effect required mixing (dissolution), and which is easy to handle.

Disclosure of the Invention

In order to achieve the above object, the present invention is based on the common arrangement disclosed in the second and third prior art examples.

More specifically, the invention is premised on an arrangement which comprises a first containing member including a first chamber having a discharge port and containing a first substance therein; a second containing member containing second substance and including a piercing section; and communication means including a piercing element capable of piercing the piercing section of the second containing member with a predetermined piercing resistance, as required, and a closing section extending into the first chamber and adapted normally to cut off the communication between the first chamber and the piercing element, the closing section being separable as required so that the communication is allowed when the closing section is separated, whereby sterile communication between the first and second chambers is effected

as required.

Based on the arrangement described above, according to the present invention, a separate storage container is proposed which is characterized by comprising: holding means disposed between the second containing member and the first chamber and surrounding the piercing element, and adapted normally to keep the piercing section of the second containing member and the piercing element separated and to undergo plastic deformation in the axial direction of the piercing element when subjected to an external force of a value greater than a predetermined value in the axial direction, thereby allowing the piercing element to pierce the piercing section and maintaining the pierced state, whereby the closing section of the communication means is separated after the piercing section is pierced by the piercing element, so that the sterile communication between the first and second chambers is effected through the communication means.

With the arrangement described above, the holding means can positively keep the piercing element of the communication means separated from the piercing section of the second containing member, so that an unexpected wrong piercing operation can be prevented. When in essential use, the holding means is plastically deformed by somewhat strongly applying the external

force or an operator's manual force to a value greater than the predetermined value, so that the piercing operation can be effected, and the pierced state can be securely maintained by the plastically deformed holding means.

Thus, the separate storage container of the present invention is simple in construction due to its few components, and its communicating portion, which constitute the communication means, is sealed to be kept sterile. Further, a guide cover, which constitutes the holding means, cannot be plastically deformed unless it is subjected to an axial external force of a value greater than the predetermined value, so that a piercing needle, which constitutes the piercing element of the communicating portion, can hardly be unexpectedly run through the piercing section by mistake. Since there is no empty bag or the like, moreover, the dissolving operation is easy.

According to a preferred specific arrangement of the present invention, the predetermined value of the external force to subject the holding means to the plastic deformation is set to be greater than the piercing resistance of the piercing element piercing the piercing section, e.g., to 3 kgf or more, preferably within the range of 3 kgf to 5 kgf, further preferably to 3.5 kgf.

Preferably, moreover, the holding means is composed of a bellows-like guide cover integrally formed from thermoplastic resin by blow molding, for example. According to the blow molding, in particular, outwardly projecting crest portions of the bellows-like guide cover can be easily formed thinner than inwardly recessed bottom portions, so that a desirable property for the guide cover can be obtained.

Other preferred specific arrangements and advantages of the present invention will be understood from the accompanying drawings and the following description taken in conjunction with the drawings.

Brief Description of the Drawings

Figs. 1 to 4 show one embodiment of the present invention, in which Fig. 1 is a perspective view of a medicine storage container wrapped in a package, Fig. 2 is an enlarged perspective view of the medicine storage container with the package of Fig. 1 removed therefrom, Fig. 3 is an enlarged longitudinal sectional view of the medicine storage container shown in Fig. 2, especially portions corresponding to a guide cover and communication means and Fig. 4(a), 4(b), 4(c) and 4(d) are illustrative diagrams for individually showing states of operation of the medicine storage container; and

Fig. 5 is a perspective view of a medicine storage container according to another embodiment of the present invention.

Best Mode of Carrying Out the Invention

Embodiments of the present invention will now be described in detail with reference to the accompanying drawings.

Fig. 1 is a perspective view of a medicine storage container as a separate storage container of the present invention wrapped in a package, and Fig. 2 is a perspective view of the medicine storage container. In both these drawings, numeral 1 denotes the medicine storage container, and the medicine storage container 1 comprises a storage chamber 2 and a housing chamber 3 which are integrally formed of a flexible synthetic resin sheet and are independent of each other. This medicine storage container 1 is entirely covered by a rectangular package 4, which ensures the stability of a solution S (mentioned later) for use as a solvent sealed in the storage chamber 2. The storage chamber 2 contains 50 to 100 ml of the solution S, e.g., a physiological saline solution or 5 % grape sugar solution. In Fig. 2, a discharge port 5 is provided at the lower portion of the storage chamber 2, and further, an aluminum cap 6 is fitted

on the discharge port 5 so that the solution S cannot run out.

A hole 1a, which is used to hang the container 1 on a hanger 14 of a transfusion stand 13 mentioned later, is formed at one end portion of the container, and a boundary portion 1b for dividing the two chambers 2 and 3 is formed at the middle portion. A communicating section 9 as communication means is disposed between the upper portion of the storage chamber 2 and the lower portion of the housing chamber 3. The communicating section 9 has a separable closing section 7 located in the storage chamber 2 and a bottle needle or piercing needle 8 as a piercing element at the distal end thereof which is located in the housing chamber 3. This communicating section is in the form of a cylinder closed at its end portion in the storage chamber 2, and a notch is formed in the inner peripheral surface so that the closing section 7 can be easily broken by means of an external force. The bottle needle 8 is provided with an angled edge 8a, which cannot be easily drawn out once it is passed through a piercing section 11 mentioned later. Further, the middle portion of the cylindrical communicating section 9 is held by means of the boundary portion 1b. A glass or plastic vial or solute vessel 10, which constitutes a solute containing

member, is housed in the housing chamber 3, and an antibiotic A as a powdered solute is contained in a chamber 10b in the vial 10. A mouth 10a of the vial 10 is fitted with a rubber stopper 11 for use as the piercing section through which the aforesaid bottle needle 8 can be run, and the stopper 11 is fixed by means of a mouthpiece 11a (Fig. 3). A bellows-like guide cover 12 is provided between the mouth 10a of the vial 10 and a bottom portion 3a of the housing chamber 3 defined by the boundary portion 1b as in Fig. 2. This guide cover 12 constitutes holding means. The guide cover 12 is formed of a material, e.g., a metal material such as aluminum or a thermoplastic resin such as polypropylene, which undergoes plastic deformation when subjected to an external force of a value greater than a predetermined value in the axial direction of the bottle needle 8, that is, in a direction such that the bottle needle 8 of the communicating section 9 pierces the rubber stopper 11 fitted in the mouth 10a of the vial 10, by an operator's hand, for example. Unless subjected to an axial force of a value greater than the predetermined value, therefore, the bottle needle 8 is kept at an off position, as shown in Fig. 3, in which it never pierces the rubber stopper 11, and the solution S cannot enter the vial 10 by mistake.

Further, the bottle needle 8 is guided by the guide cover 12 so that it is prevented from misguidedly piercing any other object than the rubber stopper 11. Once the guide cover 12 is deformed and contracts, moreover, it maintains the deformed state as a result of the plastic deformation, so that the penetration of the bottle needle 8 can be secured.

As shown in Fig. 3, one end portion 12a of the guide cover 12 surrounds the mouth 10a of the vial and the rubber stopper 11 and is fixed to the vial 10. The other end portion 12b of the guide cover 12 extends in the axial direction of the bottle needle 8 so as to surround the needle, and is fixed to the bottom portion 3a.

If the guide cover 12 is blow-molded from the a thermoplastic resin, it can get better expansion and contraction because crest portions 12c of the guide cover 12, which project radially outward, are thinner than bottom portions 12d which are recessed radially inward, as shown in Fig. 3.

It is to be desired that the predetermined value of the external force which causes the plastic deformation of the guide cover 12 should be set to a value equal to or greater than the resistance against the needle 8 piercing the rubber stopper 11 of the vial 10, that is, piercing resistance.

Since the aforesaid piercing resistance is usually about 3 kgf, the predetermined value for the guide cover 12, in this case, is preferably set to 3 kgf as a minimum value. the upper limit of this predetermined value corresponds to the external force the operator can apply. In consideration of the ease of operation, the predetermined value is set within the range of 3 kgf to 5 kgf, preferably to 3.5 kgf.

If the guide cover 12 is formed from a metal material, the method of press-molding is preferably used.

Referring now to Fig. 4(a), 4(b), 4(c) and 4(d), how to use the medicine storage container 1 with the aforementioned construction will be described.

First, the package 4 covering the medicine storage container 1, as shown in Fig. 1, is removed. Then, the bottle needle 8 of the communicating section 9 is run (see Fig. 4(a)) through the rubber stopper 11 in the mouth 10a of the vial 10 in the housing chamber 3 by axially contracting the guide cover 12 through plastic deformation by means of an external force of a value greater than the predetermined value. Further, the closing section 7 of the communicating section 9 is broken or separated so that the vial 10 and the storage chamber 2 are caused to communicate by means of the communicating section 9 (see Fig.

4(b)). Subsequently, the solution S sealed in the storage chamber 2 is injected through the communicating section 9 into the vial 10 by holding the storage chamber 2 above the vial 10, whereby the powdered antibiotic A in the vial 10 is dissolved. The resulting solution of the powdered antibiotic A is returned to the storage chamber 2 by holding the vial 10 above the storage chamber 2. By repeating such operation, the powdered antibiotic A in the vial 10 is fully dissolved (see Fig. 4(c)).

The medicine storage container 1 is hung on the hanger 14 of the transfusion stand 13 in a manner such that the hanger 14 is passed through the hole 1a of the medicine storage container 1 (see Fig. 4(d)). In other words, the medicine storage container 1 is hung on the hanger 14 so that the storage chamber 2, which contains the solution of the powdered antibiotic A, is on the bottom side. A transfusion set 15 comprises a bottle needle 16 piercing the discharge port 5, a drip cylinder 17, a clamp 18, an intravenous needle 19 to be stuck into a vein or the like of a patient M, and a tube 20 connecting these elements.

As shown in Fig. 4(d), the intravenous needle 19 of the transfusion set 15 is stuck into the vein or the like of the patient M, the bottle needle 16

is run through the discharge port 5 after removing the aluminum cap 6 fitted on the discharge port 5, and the clamp 18 is adjusted so that the solution of the powdered antibiotic A in the storage chamber 2 of the medicine storage container 1 can be administered to the patient M by an intravenous drip.

The package 4 (Fig. 1) may be removed after the antibiotic A is dissolved in the solution S by the aforementioned piercing operation and before the setting on the transfusion stand 13.

Fig. 5 shows another embodiment of the present invention. Since this embodiment is constructed substantially in the same manner as the embodiment shown in Fig. 2, like reference numerals are used to designate the same portions, and a description of those portions is omitted. In the embodiment shown in Fig. 2, the medicine storage container 1 comprises the storage chamber 2 and the housing chamber 3 which are integrally formed of the flexible synthetic resin sheet and are independent of each other. In the present embodiment, however, the storage chamber 2 and a housing chamber 30 are formed separately. The housing chamber 30 is in the form of a cylinder having a bellows-like portion 30a formed on the outer peripheral surface thereof. A hanging ring 21 is attached to an end face of the housing chamber 30.

Other arrangements and functions of this embodiment are the same as those of the embodiment shown in Fig. 2, so that a description thereof is omitted. The bellows-like portion 30a serves to secure the axial plastic deformation of the guide cover 12 and the piercing state of the piercing element 8.

According to the present invention, the piercing section and the piercing element may be disposed on the storage-chamber side and on the solute-vessel side, respectively, in contrast with the arrangement of the storage chamber 2 and the solute vessel 10 disclosed in connection with the embodiments described above. Moreover, various modifications may be effected in the present invention without departing from the spirit thereof, and the invention is not limited to the arrangements of the embodiments.

Industrial Availability

As described above, the separate storage container according to the present invention is suitably used as a drip bag adapted to be connected to a transfusion set, whereby a medicine is administered to a patient by an intravenous drip. However, the separate storage container of the invention may be also widely utilized in other fields where powdered or liquid solutes, as well as medicines, must be sterilely dissolved

in solvents.

Thus, the present invention may be applied to any other fields than the medical field in which medicines and the like are handled. Although the medicine storage container is disclosed as an example of the separate storage container of the present invention, in connection with the embodiments, the range of application of the invention is not limited to the field associated with "medicines" in a narrow sense.

CLAIMS

1. In a separate storage container comprising:
a first containing member including a first chamber having a discharge port and containing a first substance therein;

a second containing member including a second chamber containing a second substance and a piercing section; and

communication means including a piercing element capable of piercing the piercing section of said second containing member with a predetermined piercing resistance, as required, and a closing section extending into said first chamber and adapted normally to cut off the communication between said first chamber and the piercing element, said closing section being separable as required so that said communication is allowed when the closing section is separated, whereby sterile communication between the first and second chambers is effected as required,

said separate storage container being characterized in that :

holding means is disposed between said second containing member and the first chamber to surround said piercing element, and is adapted normally to keep the piercing section of said second containing

member and the piercing element separated and to undergo plastic deformation in the axial direction of the piercing element when subjected to an external force of a value greater than a predetermined value in said axial direction, thereby allowing the piercing element to pierce said piercing section and maintaining the pierced state; and the closing section of said communication means is separated after the piercing section is pierced by said piercing element, so that the sterile communication between the first and second chambers is effected through the communication means.

2. The separate storage container according to claim 1, characterized in that said predetermined value of the external force to subject said holding means to the plastic deformation is greater than the piercing resistance of the piercing element piercing the piercing section.

3. The separate storage container according to claim 2, characterized in that said predetermined value of the external force to subject said holding means to the plastic deformation is 3 kgf or more.

4. The separate storage container according

to claim 2, characterized in that said predetermined value of the external force to subject said holding means to the plastic deformation is set within the range of 3 kgf to 5 kgf, preferably to 3.5 kfg.

5. The separate storage container according to any one of claims 1 to 4, characterized in that said holding means is composed of a bellows-like guide cover.

6. The separate storage container according to claim 5, characterized in that said guide cover has one end portion, surrounding the piercing section of said second containing member and fixed to said second containing member, and the other end portion axially extending from said one end portion so as to surround the piercing element and fixed to a boundary portion dividing said first chamber and a housing chamber housing the second containing member.

7. The separate storage container according to claim 6, characterized in that said communication means includes a central portion fixed liquid-tight to said boundary portion, a distal end portion fitted with the piercing element, and a communicating portion having a proximal end portion with said closing

section.

8. The separate storage container according to claim 5, characterized in that said guide cover is integrally formed from a thermoplastic resin by blow molding.

9. The separate storage container according to claim 5, characterized in that outwardly projecting crest portions of said bellows-like guide cover are thinner than inwardly recessed bottom portions.

10. The separate storage container according to claim 5, characterized in that said guide cover is integrally formed from a metal material by the method of press molding.

11. The separate storage container according to claim 1, characterized in that said first chamber is formed from a synthetic resin sheet, and said housing chamber housing said second housing member is integrally formed inside said sheet.

12. The separate storage container according to claim 1, characterized in that said first chamber is formed from a synthetic resin sheet, and said

housing chamber housing said second housing member is formed from a synthetic resin sheet independent of said sheet, said second sheet having a bellows-like portion on the outer peripheral surface thereof.

13. The separate storage container according to claim 1, characterized in that said piercing element is formed of a piercing needle having an angled edge.

14. The separate storage container according to claim 1, characterized in that said first substance is a solvent, said solvent being contained in a storage chamber constituting said first chamber, and said second substance is a solute to be dissolved by said solvent, said solute being contained in said second chamber defined inside a solute containing member constituting the second containing member.

15. The separate storage container according to claim 14, characterized in that said solvent is a solution, and said solute is a powdered medicine.

FIG. 1

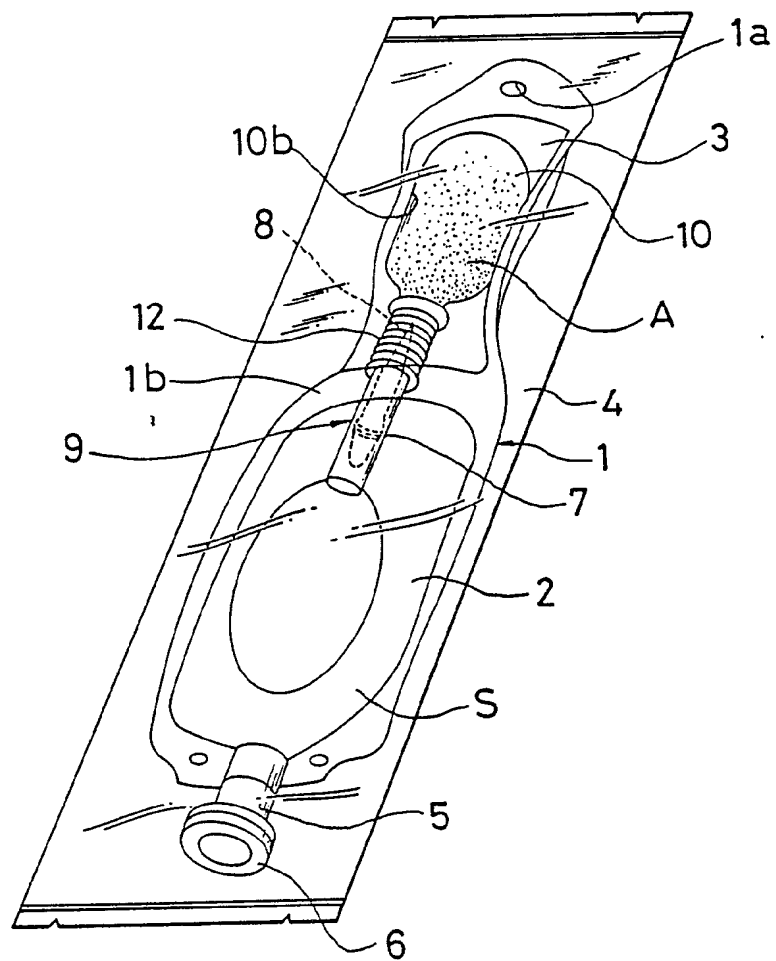


FIG.2

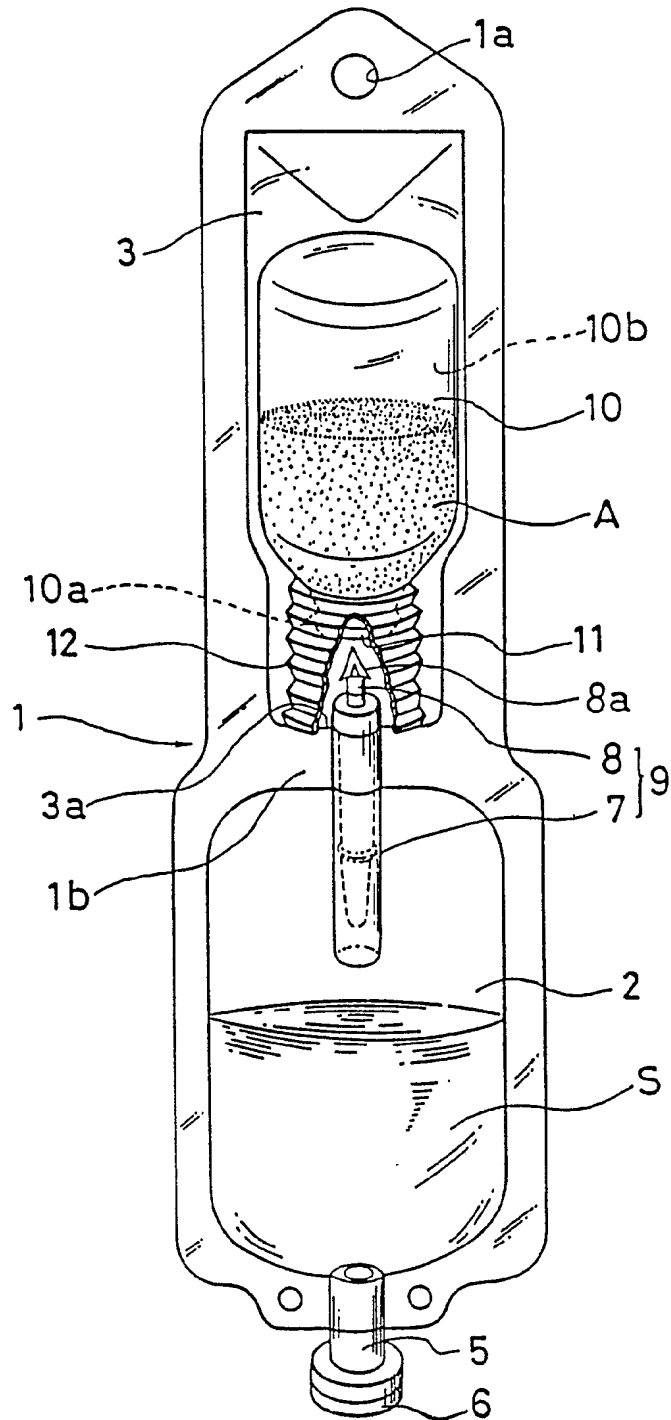


FIG. 4

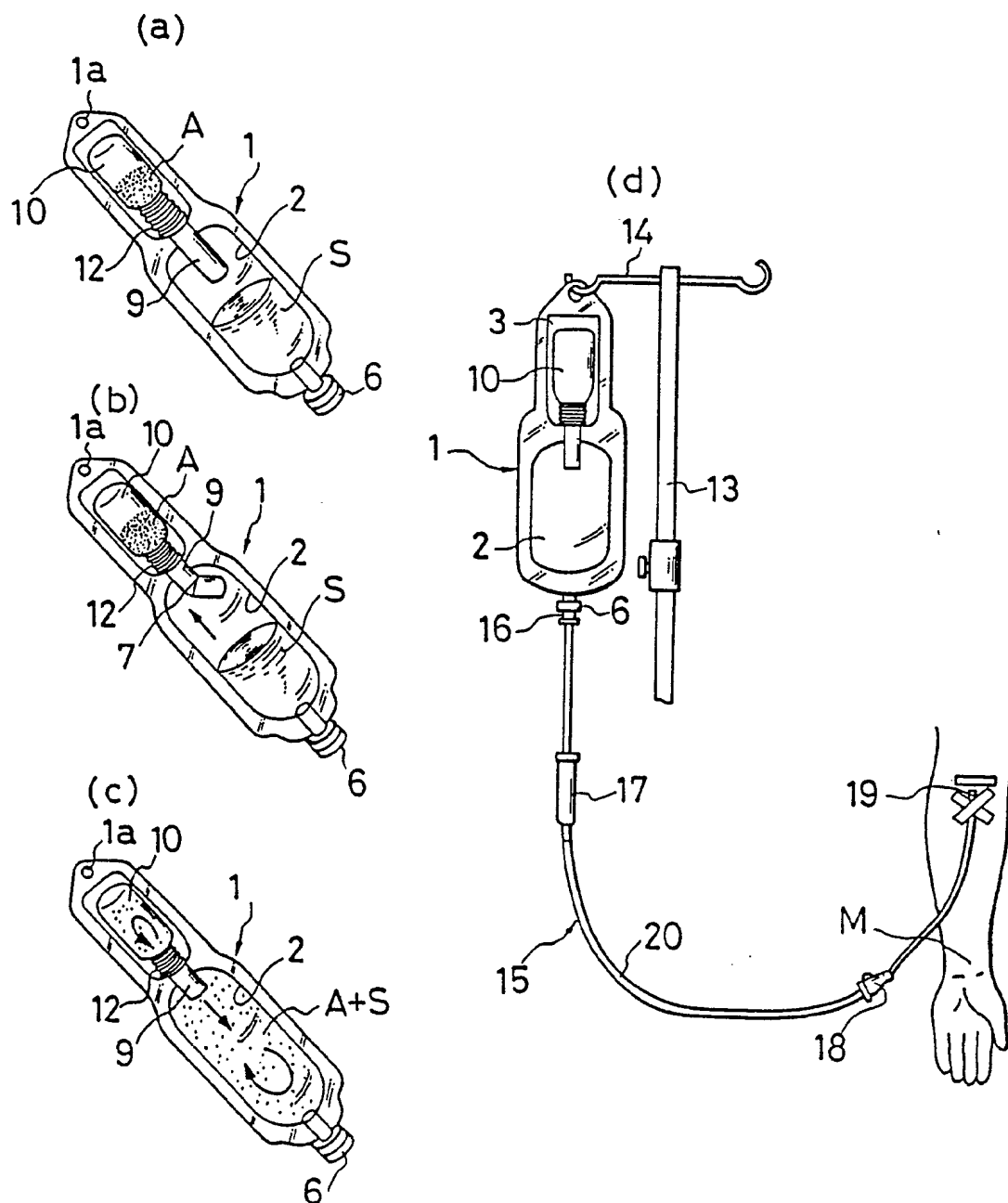
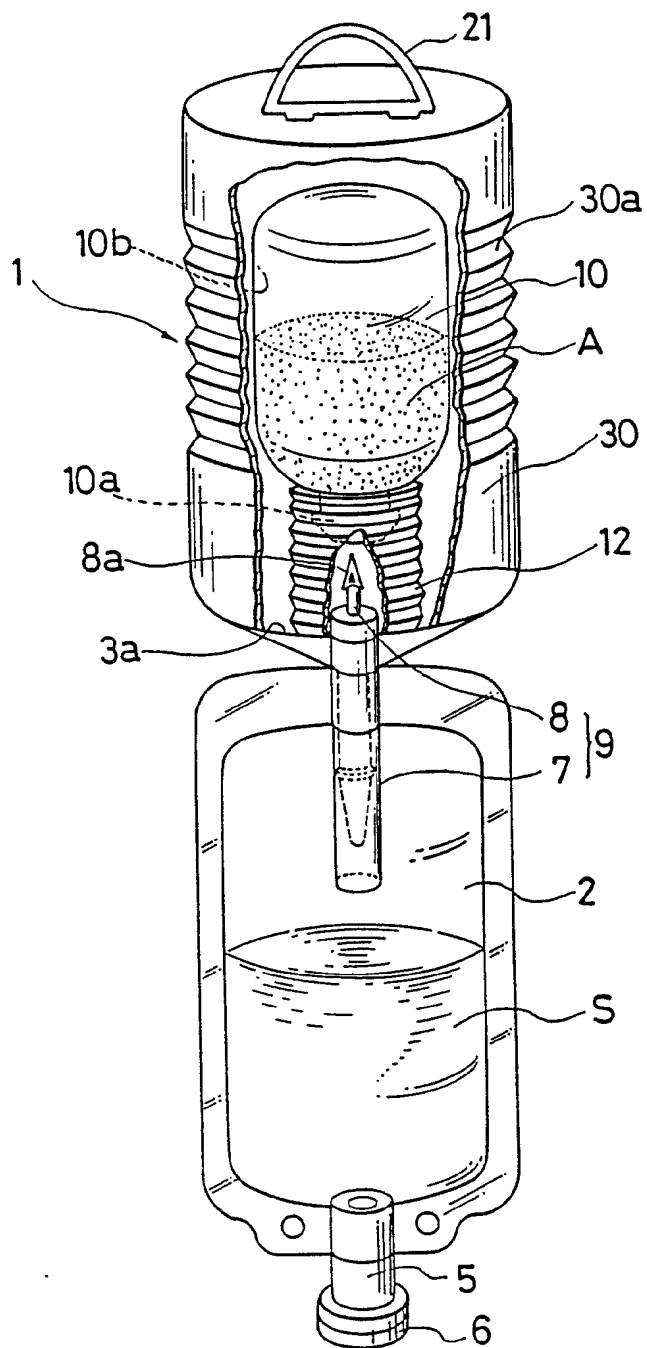


FIG. 5



INTERNATIONAL SEARCH REPORT

International Application No PCT/JP88/00980

I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all) ⁶		
According to International Patent Classification (IPC) or to both National Classification and IPC		
Int.Cl ⁴	A61J1/00, B65D25/08	
II. FIELDS SEARCHED		
Minimum Documentation Searched ⁷		
Classification System	Classification Symbols	
IPC	A61J1/00, B65D25/08	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ⁸		
Jitsuyo Shinan Koho	1946 - 1988	
Kokai Jitsuyo Shinan Koho	1971 - 1988	
III. DOCUMENTS CONSIDERED TO BE RELEVANT ⁹		
Category [*]	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³
X	JP, A, 57-500412 (Baxter Travenol Laboratories, Inc.) 11 March 1982 (11. 03. 82) Fig. 7 (Family: none)	1-4
X	JP, B1, 50-23551 (Terumo Corporation) 08 August 1975 (08. 08. 75) Fig. 3 (Family: none)	1-4
X	JP, B1, 45-36120 (Gilbert · Schwartzman) 17 November 1970 (17. 11. 70) Fig. 2 (Family: none)	1-15
X	JP, Y2, 56-1559 (Ihara Chemical Industry Co., Ltd.) 14 January 1981 (14. 01. 81) Figs. 1 to 2 (Family: none)	1-15
<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p>[*] Special categories of cited documents: ¹⁰</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> </div> <div style="width: 50%;"> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</p> <p>"&" document member of the same patent family</p> </div> </div>		
IV. CERTIFICATION		
Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report	
December 12, 1988 (12. 12. 88)	December 26, 1988 (26. 12. 88)	
International Searching Authority	Signature of Authorized Officer	
Japanese Patent Office		

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

X	JP, Y1, 43-31107 (Nikka Kogyo Kabushiki Kaisha) 17 December 1968 (17. 12. 68) Fig. 4 (Family: none)	1-15
X	JP, Y2, 60-14708 (Lion Corporation) 10 May 1985 (10. 05. 85) Figs. 1 to 2 (Family: none)	1-15

V. ☐ OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE¹⁰

This international search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

1. ☐ Claim numbers....., because they relate to subject matter¹² not required to be searched by this Authority, namely:

2. ☐ Claim numbers....., because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out¹³, specifically:

VI. ☐ OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING¹¹

This International Searching Authority found multiple inventions in this international application as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.

2. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:

3. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:

4. ☐ As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

☐ The additional search fees were accompanied by applicant's protest.

☐ No protest accompanied the payment of additional search fees.